



CREDENCE MEDSYSTEMS, INC & THE CREDENCE COMPANION SAFETY SYRINGE SYSTEM

Featuring for the first time in ONdrugDelivery Magazine, John A. Merhige, Chief Commercial Officer, Credence MedSystems, introduces the Credence Companion Safety Syringes System. This innovative, modular technology provides fully customisable needle safety without coming into contact with the drug prior to use and without any change to the existing primary drug container.

CREDENCE MEDSYSTEMS, INC

Credence MedSystems is focused on delivering medications safely for the benefit of our patients, caregivers and biopharmaceutical partners. The Credence team brings curiosity, a fresh perspective and an intense desire to understand the needs of both the end-user and pharmaceutical manufacturer to the overriding goal of improving patient care.

THE CREDENCE COMPANION SAFETY SYRINGE SYSTEM – INNOVATION WITHOUT CHANGE

The Credence Companion Safety Syringe System offers best-in-class drug delivery and a vastly simplified path to

“Credence understands that the journey (the path to commercialisation) is as important as the destination (the end product)”

market for our biopharmaceutical partners. This philosophy of *Innovation Without Change* resonates throughout Credence and is applied to the design of the Companion as well as to the company’s partnering business model. By offering the innovation

of the final device without the traditional primary packaging changes that require substantial development and regulatory work, Credence MedSystems has shifted the paradigm for commercialising a drug in a differentiated delivery system. Credence understands that the journey (the path to commercialisation) is as important as the destination (the end product).

THE JOURNEY: A SIMPLIFIED COMMERCIALISATION PATH FOR OUR BIOPHARM PARTNERS

Drug manufacturers face significant obstacles in the effort to make improvements to existing products or launch new drugs in advanced delivery systems. This is due to the development and regulatory effort traditionally required to modify a drug/device combination product. While the resulting resistance to change is understandable and often warranted, it has had the undesirable effect of keeping technological advances in delivery systems out of the market.

The Credence Companion addresses this challenge with its modular approach, thereby significantly simplifying the commercialisation path. Biopharm manufacturers have complete freedom to choose and source the critical syringe, plunger/stopper and tip-cap primary package components from any vendor(s) they choose. The Companion plunger rod, Flex



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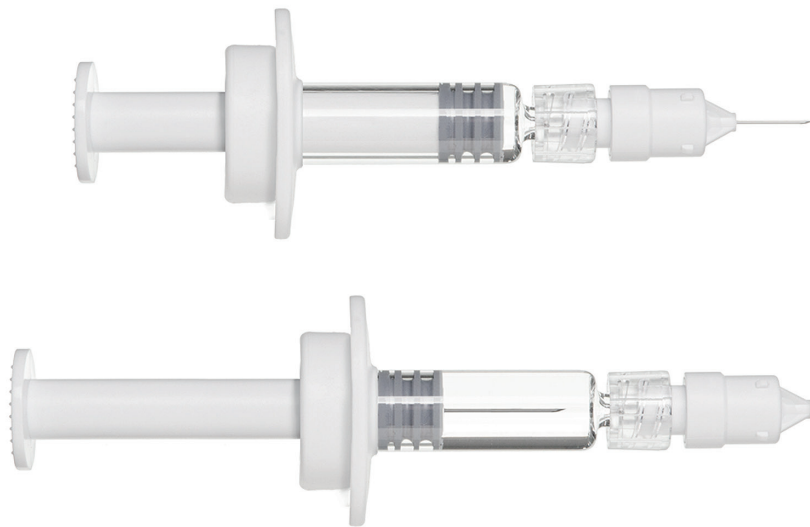


Figure 1: At the completion of the injection, the needle automatically retracts into the barrel of the syringe and the device is permanently disabled.

Finger Flange and Guide-On Needle components accompany and ‘snap on’ to the pre-filled syringe. The primary drug container is undisturbed and there is no contact between Companion components and the drug product prior to use. This approach dramatically impacts the development requirements and reduces the sourcing risk for the biopharm partner. The Companion offers drug companies a new option to differentiate their products while delivering the best technology available to their patients and providers.

THE DESTINATION: A BEST-IN-CLASS DRUG DELIVERY DEVICE

Safety and Compliance:

For the end-user, the Companion Syringe is a best-in-class safety device with passive needlestick prevention features. The user can perform standard air bubble removal and aspiration techniques without fear of prematurely engaging the safety mechanism. At the completion of the injection, the device provides visual, audible and tactile cues and the needle automatically retracts into the barrel of the syringe (see Figure 1). The syringe is then automatically and permanently dis-

abled from future use. The Companion allows the choice of any size needle (Figure 2), offering passive safety even with long needles – 2” (5.1 cm) and beyond if needed. This is unique in the market.

DIFFERENTIATION THAT GOES BEYOND NEEDLESTICK PREVENTION

Reconstitution:

Conventional safety devices often fail in lyophilisation applications due to premature activation of the safety features during reconstitution of the drug product. When the Companion is pre-filled with a diluent, the user can deliver the solution into the vial for reconstitution and then draw the reconstituted drug product back



Figure 2: The Companion allows passive safety with any size needle. This is unique in the market.

into the syringe, all while maintaining the passive safety intact for the subsequent injection into the patient (Figure 3).

Connection Integrity:

Credence has developed the Guide-On Needle Cover to address the prevalence of poor luer connection issues between conventional needles and syringes. These failures, whether from inadequate design and instructions or user error, have serious consequences including inaccurate dosing, wasted drug product, and needles being left in patients. The Guide-On Needle Cover will not allow the needle to be exposed until it has been attached properly and then provides the user audible, tactile and visual feedback that the connection is secure (Figure 4).

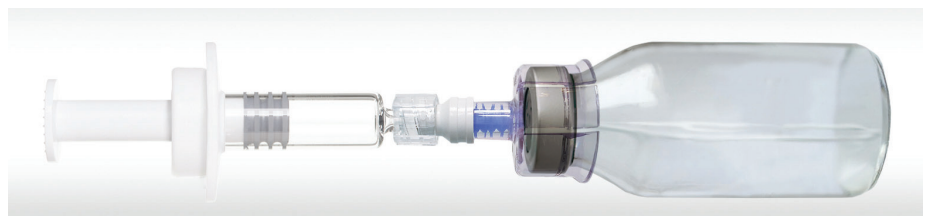


Figure 3: The safe solution for reconstitution applications – conventional reconstitution with passive safety.

“By offering the innovation of the final device without the traditional primary packaging changes that require substantial development and regulatory work, Credence has shifted the paradigm for commercialising a drug in a differentiated delivery system”



Figure 4: The Guide-On Needle Cover provides “Click” confirmation that the needle is secure.

CUSTOMISATION & FLEXIBILITY: IN THE PRODUCT & THE BUSINESS MODEL

In addition to the Companion’s safety and usability end-user benefits, vast opportunities exist to customise the design for

“The Companion plunger rod, Flex Finger Flange and Guide-On Needle components accompany and ‘snap on’ to the prefilled syringe.

The primary drug container is undisturbed and there is no contact between Companion components and the drug product prior to use”

the specific requirements of the application (Figure 5). Credence can incorporate various needle sizes, Flex Finger Flange and thumb pad designs, materials, colours and packaging configurations, all without deviating from the core modular approach of the Companion design.

This passion for offering our partners *Innovation Without Change* extends to our business model and the supply chain flexibility it provides. Just as our biopharm partners have the freedom and flexibility to choose and source the critical primary package components of the syringe, they also have complete freedom to choose their preferred moulding and assembly partners. Credence provides its expertise in technology transfer and automation to deliver a seamless integration into the filling line.

Credence approaches every challenge with the philosophy of offering *Innovation Without Change* in order to improve patient care by truly addressing the needs of both the end-user and our pharmaceutical manufacturer partners.



Figure 5: Customisable designs: Credence can incorporate various needle sizes, Flex Finger Flange and thumb pad designs, materials, colours and packaging configurations.

THE CREDENCE COMPANION

SAFETY SYRINGE SYSTEM

Please reach out to John A Merhige to discuss how Credence and the Companion can help bring *Innovation Without Change* to your drug product.

This product has not been evaluated by the US FDA.



IN WHICH EDITION COULD
YOUR COMPANY APPEAR?
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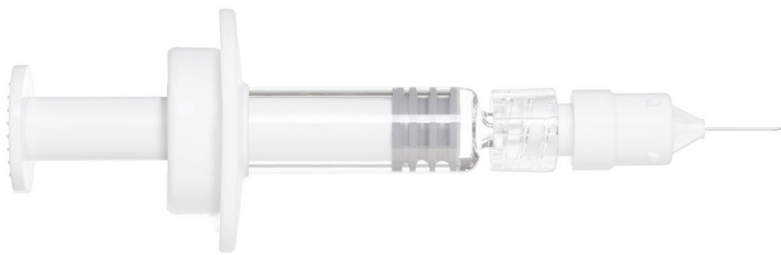
THE CREDENCE COMPANION

SAFETY SYRINGE SYSTEM

WE INVITE YOU TO LEARN ABOUT
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UNIVERSE OF PREFILLED SYRINGES
OCTOBER 6TH-7TH BOOTH #704
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YOU CHOOSE YOUR PRIMARY PACKAGE COMPONENTS.
THE COMPANION'S MODULAR 'SNAP-ON' APPROACH
SIMPLIFIES THE DEVELOPMENT PATH.



THE NEEDLE PASSIVELY RETRACTS INTO THE BARREL,
AUTOMATICALLY DISABLING THE SYRINGE.



COMPANION GUIDE-ON NEEDLE



YOUR PRIMARY PACKAGE COMPONENTS



COMPANION PLUNGER ROD

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